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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,733	02/14/2002	Ulrich Behrendt	21102 US	1652

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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EXAMINER

MENON, KRISHNAN S

ART UNIT PAPER NUMBER

1723

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,733

Applicant(s)

BEHRENDT ET AL.

Examiner

Krishnan S Menon

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25, 26, 42-44 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 25, 26, 42-44 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-23, 25,26, 42-44 and 47 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-4, 6, 10-12, 19, 21, 25,43 and 47 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Zha et al (US 6,524,481 B2).

Claim 1: Zha (481) teaches a hollow fiber membrane module (figures) comprising a housing (9, Fig 5A,B; col 7 lines 57-64), plurality of hollow fibers (6) arranged parallel, wherein the volumetric ratio of the membranes to packing space is less than 10% (col 4 lines 27-29, claims 13, 14). The RCE/amendment of 6/9/04 clarifies that the plurality of hollow fiber membranes is situated in the annular space, with the membrane pack density <10% specific for the annular space. Col 7 lines 57-64 of the reference also teaches that the embodiment of Fig 5A and B has membrane only in the annular space (passage 24 is described as a central membrane-free zone), and therefore, the pack density as defined by col 4 lines 27-29 would apply only to the annular space. Even if

one argues that the packing density defined by Zha was for the entire space within the housing, since the claim does not specify the first outer radius R_1 , a calculation with a reasonable value for the first outer radius as 2, and the second outer radius as 10, the annual space area would be 96π , and the 5% packing density of Zha would only increase slightly ($5\% \times 100/96$, would be $< 10\%$).

Housing is cylindrical as in instant claim 2 (fig 3B, 4B). Lateral housing surface has openings as in instant claim 3 (9-fig 1-4) having shapes squares, etc as in instant claim 4 (51-fig 9). Ratio of opening area to housing surface area is about 0.2 to 0.9 as in instant claim 6 (see figures and col 4 lines 29-34). The fibers are arranged in the form of a bundle as in instant claim 10 (figures). At least two fiber bundles are separated by a segmentation element fitted on the lateral surface of the housing as in instant claim 12 (see fig 9, 10). The length of at least one segmentation element corresponds to the length of the housing as in instant claim 19 (figures, col 8 lines 20-27). Segmentation elements are as long as the pottings provided at the ends, and the pottings are segmented as in instant claim 21 (Fig 9). Module comprises connections for feeding liquid into and withdrawing from the hollow fiber as in instant claim 25 (fig 7,8). Regarding claim 43, the low range of packing density, below 20% (col 4 lines 27-29), with the 2 mm fiber diameter would make the fiber count less than 10 per centimeter (The examiner believes this should be square centimeter, and is assumed as such for examination). Claim 47: hollow fibers have same diameter – see col 4 lines 34-40.

2. Claim 11 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by, or in the alternative, under 35 USC 103(a) as unpatentable over Zha et al (US 6,524,481 B2).

Claim 11 is a product by process claim having structural elements as in claim 10, and therefore, is not patentable. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zha (481).

Zha (481) teaches all the elements of claim 5 as in claim 3 above, except the size of the openings on the lateral surface of the housing. However, it would be obvious to one of ordinary skill in the art at the time of invention to provide openings of

about 3 to 20 mm on the screen type housing of Zha (see 9, figures) to prevent excessive movement of the fibers and to have clear flow passage.

2. Claims 13 – 16, 20 and 22-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Zha (481) in view of Young et al (US 5,282,964).

Zha (481) teaches the elements of the instant claims as in claim 10 above, except: segmentation elements having a frame surrounding a free passage surface as in claim 13, the frame subdivided into stabilization elements as in 14, ratio of openings to total surface area of the stabilization elements being 2-20% as in claim 15, segmentations elements fitted to the inner surface of the housing to subdivide into compartments as in claim 16, segmentation elements shorter than the housing as in claim 20, hollow fibers arranged in compartments produced by segmentation elements as in claim 22 and fixed on the segmentation elements as in claim 23.

Young teaches a housing with segmentation elements attached on the inner surface of the housing, segmentation elements shorter than or equal in length to the housing, dividing the housing into compartments and having hollow fiber bundles contained in the compartments (see fig 3, parts 32, 30). Young teaches the segmentation elements and the housing to be impervious. However, it would be obvious to one of ordinary skill in the art at the time of invention to have the housing and segmentation compartment construction of Young in the module of Zha (481) with the material of the housing and the segmentation elements as the lattice type screen of Zha (481) for supporting the hollow fibers and preventing excessive movements of the

hollow fibers while providing free passage for the fluids and air bubbles as taught by Zha (see figure 9 and col 8 lines 12-27).

3. Claims 7-9, 26 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zha (481) in view of EP 1 008 358 A2

Zha (481) teaches all the elements of the instant claims as in claim 1 above except the material of the hollow fiber as in claim 7, and material capable of sterilizing at 121°C as in claim 26. EP (358) teaches polymeric (polysulfones, cellulosic, etc) hollow fiber membranes (see specification of EP). It would be obvious to one of ordinary skill in the art at the time of invention to use the polymeric hollow fiber as taught by EP (358) in the teachings of Zha (481) for the module for having hydrophilic material for application like water treatment. Regarding the material being resistant to steam at 121°C, the material taught by EP(358) is the same as what the instant application recites, and therefore, should withstand the same temperature.

Claims 8, 9 and 42 have additional elements which are taught by Zha (481) as follows: Thickness of membrane from 5 to 300 microns as in claim 8, inside diameter less than 2 mm as in claims 9 and 42 of 0.15 to 0.8 mm (col 4 lines 35-40).

4. Claims 17, 18 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zha (481) in view of Young et al (US 5,282,964) as in claim 12 above and further in view of Smoot et al (US 4,689,255).

Zha (481) in view of Young (964) does not teach segmentation elements fitted to the outer surface of a housing as in claim 17. Smoot teaches arranging hollow fiber bundles on a pervious sheet (1-fig 2) and then wrapping on the outside surface of a perforated housing (tube) (12 fig 3) (see col 3 line 47 – col 4 line 30). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Smoot in the teaching of Zha in view of Young to have the segmentation elements attached to the outside surface of an inner housing for further protecting the fibers from the force of the fluid flow in the construction of fig 5A and 5B of Zha (481). Regarding claim 18, which depend from claim 17, the teaching of Zha in view of Young has the second cage like structure (fig 5A, 5B and 9 of Zha). Regarding claim 44, the hollow fibers are arranged inside at least one compartment (Zha, fig 3).

Response to Arguments

Applicant's arguments filed 6/9/04 have been fully considered but they are not persuasive.

Applicants' principal argument is that the packing density of the regions having the fibers in the Zha ref is greater than 10%. Applicants attempt to prove this by an example, with arbitrary values for r_2 as 8 cm and r_1 as 6 cm. However, the claims do not limit the r_2 and r_1 values as in the example, and therefore, this argument is not persuasive. At $r_2 = 8$, for all values of $0 > r_1 > 5.65$, the 5% packing density of Zha would increase only to less than 10%, and would anticipate claim 1.

In response to applicants' argument that the Zha ref teaches away, teaching away is not applicable to anticipatory rejections [*Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998)] and "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments" (In re *Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971)).

Applicants' arguments re the invention as being immersion modules for sterile fermentation vessels, and for sterile fermentation process, etc., are not commensurate with the scope of the claims. Claim 1 is for an apparatus and recites a membrane for filtration, diafiltration, dialysis, etc.

Rest of the arguments are based on the packing density, and are already addressed above or in the rejections.

Conclusion

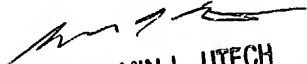
All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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